



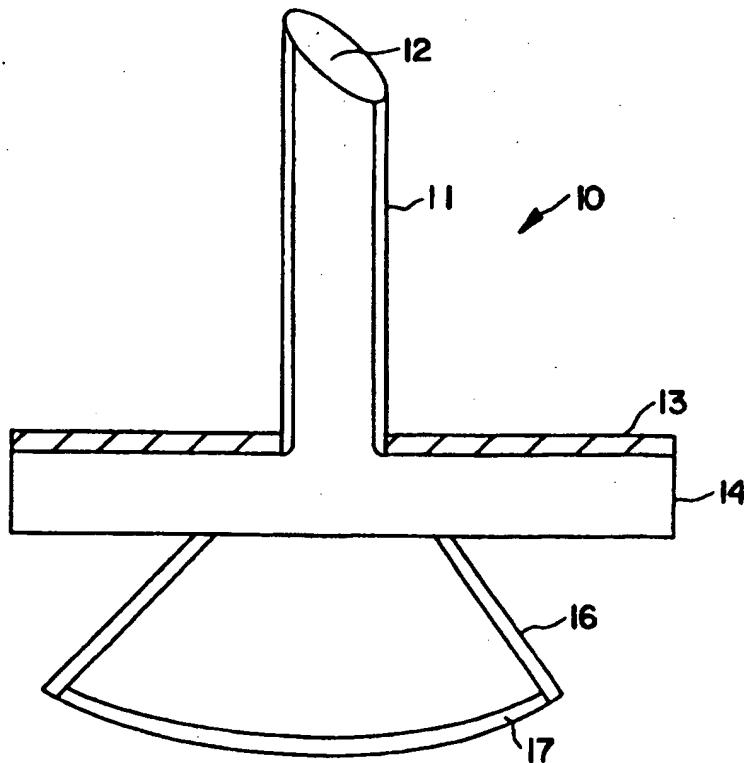
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(S4) Title: METHOD AND DEVICE FOR CONTROLLING URINARY INCONTINENCE

## (57) Abstract

This invention is a novel urinary continence device and a method of controlling urinary incontinence utilizing that device, the device comprising a housing (10), defining a lumen (12) and having a body (11) for insertion into the urethra and a plate (14), and a valving member, the plate (14) and/or the body (11) having an adhesive (13) or other sealing means thereon, wherein the adhesive (13) or other sealing means secures the device to the human body, generally to the tissues surrounding the meatus urinarius and/or to the urethral walls. The housing (10) may remain in the body for an extended period of time. The valving member blocks the flow of urine in the urethra until voiding is desired. In a preferred embodiment, the valving member is a cap (76) configured so as to form a snap fit with an internal lumen of the housing.



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**METHOD AND DEVICE FOR CONTROLLING  
URINARY INCONTINENCE**

**FIELD OF THE INVENTION**

5        This invention relates to the control of urinary incontinence *in vivo* and is directed more particularly to a urinary continence device that is inserted into the urethra by the user for an extended period, and a methodology for controlling incontinence by using such a device.

10

**BACKGROUND OF THE INVENTION**

15       Urinary stress incontinence is the involuntary loss of urine when the pressure within the urethra exceeds the maximum urethral pressure required for maintaining closure or continence. While the problem of urinary incontinence occurs in men and women, it is an affliction especially common in women of child bearing age and beyond.

20       There are in existence many methods used to address the problem of incontinence including surgical corrective techniques (e.g., bladder neck suspension surgery), surgically implanted indwelling devices, physician prescribed and inserted indwelling devices as well as externally worn devices that collect or absorb urine. Each method has its drawbacks.

25       Surgically implanted devices may not be appropriate for patients with mild incontinence, or for those with other medical conditions that place them at risk for surgery. Additionally, one must consider the somewhat prohibitive cost of surgery. There are also the problems of encrustation, irritation, infection, toxic reactions to materials and tissue necrosis with surgically implanted devices. Moreover, surgically implanted devices traditionally have a low long term success rate, and that success rate is highly dependent on the individual surgeon's technique.

30       Indwelling devices that are inserted by a physician, without involving surgical implantation, are also known. These devices are inserted by a physician through the urethral orifice and allow the wearer to void either past or through

the device. In United States Patent No. 4,553,533, there is shown a prosthetic urethral sphincter valve which is placed in the urethra and anchored in the bladder. The patient increases bladder pressure by means of a valsalva maneuver, 5 and holds this pressure while the valve activates. Urine may pass through the valve with the valve later returning to its closed position. United States Patent No. 5,352,182 describes a device that includes a valved catheter for temporary placement in the female urethra comprising a hollow shaft with 10 an extendable sealing portion on one end for placement through the urethra into the bladder and a crown on the other end for placement external of the body, and a spike for opening the valve in the catheter to allow voiding of the contents of the bladder.

15 Indwelling devices that are inserted by a physician have generally been very complicated, difficult to manufacture and therefore expensive. In practice, such devices have proven difficult to use for the wearer as they are uncomfortable and prove cumbersome to manipulate to void. Additionally, such 20 devices, if present in the bladder, can leave the wearer susceptible to bladder infection, as bacteria may be introduced into the bladder, a sterile area, during insertion. The presence of any device in the bladder may also cause abrasion in the bladder, especially during heavy exercise. 25 Additionally, these devices, because they are indwelling, may cause some of the numerous complications associated with surgically implanted devices, such as encrustation, irritation and infection.

Ideally, the problem of incontinence is addressed with a 30 device that is capable of being inserted by the wearer. There is therefore a need for a urinary continence device that is comfortable and easy for the wearer to insert yet becomes effectively anchored in the urethra and can be easily manipulated by the wearer to allow for voiding without removal 35 of the device.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide a urinary continence device that is easy to insert by the wearer.

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Another object of the present invention is to provide a urinary continence device that can be worn for an extended period of time.

10 It is another object of the present invention is to provide a urinary continence device that can be worn in comfort by the wearer for an extended period of time.

15 A further object of the present invention is to provide a urinary continence device that can be manipulated easily by the wearer to allow for voiding without disturbing the tissue-to-device bond.

Yet another object of the present invention is to enhance the anchoring and sealing ability of a urinary continence device.

20 Still another object of the present invention is to provide a urinary continence device with which the wearer can achieve a urine flow rate during voiding that approximates that of a normal urethra.

25 It is another object of the present invention to provide a urinary continence device that does not require sizing the occlusion device for a given user.

30 Another object of the present invention is to provide a urinary continence device that can be worn during a range of activities performed by the wearer, including heavy exercise, without risk of leakage and/or trauma to the body.

A further object of the present invention is to reduce the risk of contamination to the bladder for the wearer of a urinary continence device.

35 Still another object of the present invention is to provide a method for using a urinary continence device to control urinary incontinence.

These and other objects of the invention are met with a novel urinary continence device for men and women comprising a

housing having an adhesive or other securing means thereon, wherein the adhesive or other securing means secures and/or seals the housing to the tissues surrounding the *meatus urinarius*, and/or in some embodiments, to the urethral wall.

5 After insertion by the wearer, the housing may remain in the body for an extended period through multiple voidings. The housing accommodates a valving member that will block the flow of urine in the urethra until voiding is desired. In a preferred embodiment, the valving member is a cap secured to  
10 the housing by a flexible hinge.

These and other objects of the present invention will be apparent from a review of the detailed description of the preferred embodiments, taken together with the drawings, in which like reference numbers refer to like members in the  
15 various views.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a housing of a urinary continence device according to the present invention disposed in a male patient immediately following insertion with an applicator.  
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FIG. 2 illustrates a housing of a urinary continence device according to the present invention disposed in a female patient immediately following insertion with a different type of applicator.

25 FIG. 3 is a cross sectional view of a housing of a urinary continence device according to the present invention.

FIG. 4 is a perspective view of a urinary continence device according to the present invention disposed on one type of applicator for insertion into a wearer.

30 FIG. 5 is a cross sectional view of a urinary continence device according to the present invention disposed on another type of applicator for insertion into a wearer.

FIG. 6 is a perspective view of an alternative embodiment of a housing of the urinary continence device according to the present invention having sealing rings extending from the housing for enhanced anchoring and/or sealing of the device in  
35 the urethra.

FIG. 7 is a cross sectional view of a urinary continence device according to the present invention having a removable plug valving member.

5 FIG. 8 is a cross sectional view of an applicator for the device of FIG. 7, holding a removable plug valving member, prior to insertion into the device.

10 FIG. 9 is a cross sectional view of a urinary continence device according to the present invention having a limited number of uses type valving member comprising multiple occluding members, with one of the multiple occluding members shown in the occluding position to maintain continence.

15 FIG. 10 is a cross sectional view of the device of FIG. 9, with the valving member in a position enabling the wearer to void.

FIG. 11 is a cross sectional view of the device of FIGS. 9 and 10, having a second occluding member positioned so as to occlude the device.

20 FIG. 12 is a cross sectional view of another embodiment of the urinary continence device of the present invention, in an open position.

FIG. 13 is a cross sectional view of still another embodiment of the urinary continence device of the present invention.

25 FIG. 14 is a perspective view of the valving member of the device of FIG. 13.

FIG. 15 is a cross sectional view of the preferred embodiment of the urinary continence device of the present invention, in an open position.

30 FIG. 16 is a perspective view of the device of FIG. 15 in a closed position.

FIG. 17 is a perspective view of the device shown in FIGS. 15 and 16, ready for insertion in a wearer, on an applicator particularly suitable for use with this embodiment of the present invention.

35 FIG. 18 is a perspective view of yet another embodiment of the urinary continence device of the present invention.

FIG. 19 is a cross sectional view of the device shown in

FIG. 18 in a closed position.

FIG. 20 is a cross sectional view of the device shown in FIGS. 18 and 19 in an open position.

5 FIG. 21 is a perspective view of another embodiment of a housing for use with a urinary continence device according to the present invention.

10 FIG. 22 is a cross sectional partial view of another embodiment of a urinary continence device according to the present invention, in a collapsed configuration prior to insertion in the human body.

FIG. 23 is a cross sectional view of the device of FIG. 22, after insertion of the valving member.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 The present invention is a novel urinary continence device comprising a housing and a valving member. The housing has an adhesive or other anchoring means thereon, wherein the adhesive or other anchoring means secures, and may seal, the housing to the human body, to the tissues surrounding the 20 *meatus urinarius* and/or to the urethral wall. The housing may remain in the body for extended periods of time through multiple voidings. The housing accommodates the valving member that will block the flow of urine in the urethra until voiding is desired.

25 As illustrated in FIGS. 1 and 2, the urinary continence device of the present invention can be used in male and female patients. It will be obvious from the discussion below that certain embodiments may be better for a patient of one sex or the other because of the configuration of the device and the 30 anatomy of the patient. The principles of the present invention, however, are applicable to both sexes.

35 FIGS. 1 and 2 show the housing 10 of the urinary continence device of the present invention in a wearer after insertion. To use the device of the present invention, the body 11 of the housing 10 is introduced into the urethra until plate 14 contacts the tissues surrounding the *meatus urinarius*.

FIG. 3 illustrates the housing 10 of the urinary continence device of the present invention in more detail. The housing 10 may be comprised of a biocompatible material such as polyurethane, polyethylene, polypropylene, nylon, 5 latex, silicone, foamed urethane, DYNAFLEX (a trademark of GLS Corporation of Cary, Illinois, for a biocompatible thermoplastic elastomer), KRATON (a trademark of Shell Chemical Company of Houston, Texas, for a biocompatible thermoplastic elastomer), cellulose, C-FLEX (a trademark of Consolidated Polymer Technologies of Largo, Florida, for a 10 biocompatible thermoplastic elastomer), polyvinylchloride and the like. Housing 10 defines a lumen 12 and has a body 11, a plate 14 and adhesive 13. Adhesive may be positioned on the plate 14, and/or it may be positioned on the body 11 for anchoring the device in the human body.

The body 11 of the housing 10 can be tubular as shown in most of the figures or it may be any geometric shape that can be comfortably and easily inserted into and retained in the urethra by the wearer. See, for example, FIG. 21. The tip of 20 body 11 distal to plate 14 may be blunt, as shown in FIG. 2, or it may be shaped for easier insertion into the urethra, for example, rounded or, preferably, tapered as illustrated with many of the embodiments. The length of the body 11 is determined so as to allow the body 11 to sit within the 25 urethra and provide a good seal between the urethral walls and the body 11 such that urine flows through the lumen 12. The length of the body 11 of the housing 10 can vary, from a length that allows the body 11 to rest immediately within the urethra at the *meatus* to a length that extends the body 11 to 30 beyond the sphincter muscle.

Housing 10 defines a lumen 12, which will provide a path for urine flow, as will be described below. The lumen 12 of the housing 10 will be sized in diameter so as to allow comfortable insertion into the urethra and to provide a pathway of substantially similar size as a normal urethra during urination to simulate normal urine flow.

A plate 14 is disposed at the end of the housing 10 and

will have a configuration that is comfortable to the wearer when in place in the meatal region and that will provide for sufficient anchoring of the housing to the wearer, as described below. For example, as shown in many of the 5 figures, plate 14 is a flanged type member and is shown in its preferred embodiment, circular. Alternatively, plate 14 may be irregularly shaped and may be larger to provide for enhanced anchoring. A larger plate 14 may be particularly suitable for use with female wearers, as plate 14 may extend 10 into the region of the labia minora, and even the vestibule floor. Additionally, the plate 14 may be concave in shape, or convex, to add to the comfort of the wearer. Plate 14 may even have some depth to it, as shown in FIG. 21. Plate 14 may be either contiguous with the body 11 or, alternatively, may 15 comprise a separate attachment to the body 11.

With reference to the alternative configurations of plate 14, the following specification describes the insertion of one embodiment of the urinary continence device of the present invention until the adhesive 13 on the plate 14 contacts the 20 tissues of the meatus urinarius. Use of the alternative configurations of the plate 14, however, will mean that the adhesive 13 on the plate may contact a larger area of the wearer's body, such as those regions described above with 25 reference to female wearers. The description below is intended to refer to those embodiments as well.

The adhesive chosen for use in the present invention can be any adhesive which comfortably bonds to tissue and can subsequently be removed. Removal may be done by mechanical force, or by the use of a releasing agent, and/or the adhesive 30 may be formulated to adhere for a predetermined amount of time, ranging from short (a few hours) to extended, and to release and allow the device to fall off after that predetermined amount of time. The releasing agent may be water-based, oil-based, or any emulsion, as is well known in 35 the art. Adhesives suitable for use in the present invention include both natural and synthetic materials. Preferred adhesives include, but are not limited to, hydrogel adhesives,

polyvinylether-based adhesives, hydrocolloid, acrylic-based adhesives and natural gum and synthetic rubber adhesives. Hydrocolloid adhesives are particularly suitable for formulation to release after a predetermined amount of time.

5 Other biocompatible adhesive materials known to those skilled in the art may also be used.

In one embodiment of the urinary continence device of the present invention, disposed on the surface of the plate 14 proximal to the body 11 is adhesive 13. The adhesive 13 may 10 be in a continuous layer or it may be present in a discontinuous layer.

In an alternative embodiment of the urinary continence device of the present invention, adhesive 13 is disposed on the external surface of body 11 of housing 10 for anchoring 15 the device in the human body. The adhesive may be present in a continuous layer or it may be present in a discontinuous layer as needed for retention in the urethra. Adhesive present on the body may also provide additional protection against urine flowing outside the lumen 12, as opposed to 20 through the lumen 12. In yet another embodiment of the device of the present invention, adhesive may be present both on the plate 14 and on the body 11. In the following specification, the device of the present invention is described and shown in most figures having adhesive 13 positioned solely on the plate 25 14. This description is for illustration only and is not intended to be limiting as the alternative embodiment described in this paragraph falls within the concepts of the present invention. Reference should be made to FIGS. 22 and 23 and the related description for a urinary continence device 30 of the present invention having adhesive 13 positioned on the body of the housing as the means to anchor the device in the human body.

The urinary continence device of the present invention 35 may be inserted into the urethra by the wearer using his or her finger, that is, without using an applicator. In a preferred embodiment, however, an applicator will be used to place the housing into a wearer. FIGS. 4 and 5 illustrate two

applicators that can be used to insert the urinary continence device of the present invention. Those skilled in the art will realize that applicators known in the field can be used with the present invention as well.

5 FIG. 4 illustrates a plug type applicator 20 having a urinary continence device according to the present invention disposed on one end thereof ready for insertion into a patient. The applicator 20 is essentially tubular. The diameter of the tubular applicator is sufficient for the  
10 applicator walls to support the housing 10 in which a valving member may or may not be positioned by the plate 14 and, in those embodiments incorporating adhesive 13 on the plate, to exert pressure on the area of the plate 14 on which the adhesive 13 rests on its opposite surface.

15 The wearer grasps the applicator 20 and guides the housing 10 into the urethra, until the plate 14 is disposed proximal to the tissue of the *meatus urinarius*. If adhesive 13 is present on plate 14, the applicator 20 applies pressure to adhesive 13 to cause the plate 14 to bond to the tissue.  
20 It will be recognizable to those skilled in the art that many configurations can be used for applicator 20. For example, the applicator 20 can have concave side walls as shown in applicator 30 in FIG. 5. In any event, an applicator usable in the present invention preferably will be configured to  
25 apply pressure in the region of the plate 14 against which the adhesive 13 is placed, so as to enhance the device-to-tissue bond, and it will disengage from the housing 10 when the adhesive 13 is secured to the tissue.

30 An alternative applicator 30 is shown in cross section in FIG. 5. Applicator 30 has applicator body 31, shown herein with concave side walls although the side walls may be substantially straight, support member 33 for supporting the housing 10 for insertion and applicator head 32. As shown the applicator 30 is one piece, although it will be instantly  
35 recognizable to those skilled in the art that the applicator 30 can be configured in an alternate arrangement. Applicator head 32 may have a post-like configuration, of sufficient

length to support the housing 10 during insertion into the human body. Alternatively, the applicator head 32 may be of sufficient length to extend through the lumen 12 of housing and out of the end of housing 10 distal to plate 14, as shown 5 in FIG. 5. In that configuration shown in FIG. 5, applicator head 32 supports the housing 10 but also provides a rounded and lubricous leading edge because of its shape, and additionally this preferred leading edge can be optimized by choice of materials chosen for applicator, such as 10 polypropylene or even TEFLO, to facilitate insertion of the applicator 30 into the urethra. As applicator head 32 provides the leading edge for insertion of the housing 10 into the urethra, housing 10 can be made more flexible and less stiff than will otherwise be required if no applicator or an 15 applicator as shown in FIG. 4 is used.

To use, the wearer places the applicator 30 through the lumen 12 of housing 10 so that applicator head 32 extends out of body 11 and plate 14 rests on support member 33. Alternatively, the applicator 30 and housing 10 may be 20 preassembled in the package for a wearer's convenience. The housing 10 will be inserted into the urethra by grasping applicator body 31 and leading applicator head 32 into the urethra until plate 14 or adhesive 13 meets the tissues surrounding the *meatus urinarius*, and where applicable, the 25 tissues and adhesive will bond. The applicator 30 can then be pulled out of the urethra and the housing 10 will remain in place.

Upon insertion, the urethral wall conforms to the shape 30 of the body 11. Adhesive 13 present on the surface of the plate 14 or alternatively on the body 11 functions to secure the housing 10 to the meatal region or the urethral wall respectively, as described above.

An additional means to anchor the body 11 against the 35 urethral walls in a wearer is shown in FIG. 6. One or more sealing rings 15, areas of larger diameter than the diameter of the body 11 and extending from the body 11 in spaced intervals, may be provided on the body 11 of the housing 10.

The urethral tissue conforms to the shape of the one or more sealing rings 15 to provide enhanced anchoring and sealing of the device in the wearer.

FIG. 3 illustrates an additional guiding member usable with a urinary continence device according to the present invention. Guiding member 16 extends from the housing 10 and may have a ridge 17 for easy gripping. Guiding member 16 may be contiguous with the housing 10 or, alternatively, may comprise a separate attachment to the device. Guiding member 16 may be formed from a biocompatible material such as polyurethane, polyethylene, polypropylene, nylon, latex, foamed urethane, silicone, DYNAFLEX, KRATON, cellulose, C-FLEX, polyvinylchloride and the like. When in use in a wearer, the guiding member 16 rests outside of the human body. The guiding member 16 will preferably be made thin and flexible so that it can collapse and fold with little force and conform to the labial region for the comfort of the wearer. It is preferably symmetrical so no orientation is required. When folded, the guiding member 16 may be used as a handle to pull or twist the urinary continence device. In that position, it also seals the lumen 12 at the plate 14 to prevent urine from getting on the wearer's hands. When the guiding member 16 is released and opened, the urine will flow freely in the aimed direction away from the adhesive bond. Additionally, guiding member 16 acts as a guide for the wearer for insertion of the valving member or manipulation of the valving member. As shown in the figures, guiding member 16 has a funnel-type shape, but one skilled in the art will recognize that a guiding member 16 can be tube-like, or may have walls flaring or narrowing and still provide the features of the illustrated guiding member 16. The guiding member 16 may be used with many of the embodiments of the present invention described below and is shown in several of them by way of illustration, but not limitation.

The housing 10 of the urinary continence device of the present invention will be inserted into the urethra, as described above. It will be inserted by the wearer, as the

services of a physician are not required. The housing 10 remains in contact with the human body through many voidings for an extended period of time. At the end of the period of time, or should the wearer choose to remove the device, the 5 wearer simply removes the housing 10, for example by peeling the plate 14 of the housing 10 off the tissue in the area of the *meatus urinarius* or by moistening the plate 14 with an appropriate releasing agent, such as a remover or even water. The seal with the body tissue at the *meatus urinarius* is thus 10 broken, and housing 10 is easily disengaged. The wearer then simply disposes of the entire urinary continence device by flushing the device or through ordinary trash disposal means.

When the urinary continence device of the present invention is in place, the wearer will manipulate a valving member, described below in its many embodiments, to void. The 15 selection of a valving member for the urinary continence device of the present invention will depend on the wearer's type of incontinence, as well as the person's ease and comfort in inserting the device, wearing it throughout the period and 20 manipulating the valving member.

Referring to FIGS. 7 and 8, it will be seen that an illustrative urinary continence device according to the present invention has a removable plug type valving member. The urinary continence device 70 includes housing 71 defining 25 a lumen 72 and having a body 73, plate 74 and adhesive 75 on the plate 74, as described above, and valving member. Valving member is a plug 76 having a plug body 77 and an appendage such as a string 78 secured to the plug body 77. The appendage may, alternatively, be a tab or extension (not 30 shown) of the plug body 77.

The plug body 77 comprises a body of biocompatible material, such as polyurethane, polypropylene, nylon, polyethylene, latex, foamed urethane, silicone, DYNAFLEX, KRATON, cellulose, C-FLEX, polyvinylchloride and the like. 35 The plug body 77 may be essentially spherical, as shown in FIG. 7, or it can be cylindrical, provided with at least one closed end that in use will face the bladder to provide

occlusion. Plug body 77 may be provided with an enlarged base portion, as shown in FIG. 8. The plug body 77 of plug 76 is of sufficient diameter to occlude the lumen 72 of housing 71.

This embodiment of the present invention will preferably include an applicator 80, shown in FIG. 8, for positioning and depositing the plug body 77 into the housing 71 in the urethra of a wearer. In its simplest form, applicator 80 comprises a tubular shell having first end 82 for supporting the plug body 77 and second end 84. Prior to insertion, as shown in FIG. 8, plug body 77 rests on first end 82 of applicator and string 78 extends through the tubular portion of the applicator 80.

For the embodiment of the present invention shown in FIGS. 7 and 8, housing 71 may have means to prevent the plug body 77 from being inserted too far or from migrating out of the housing 71 in either direction. FIG. 7 illustrates one way to prevent this movement. Extending substantially laterally and inwardly into lumen 72 in the body 73 is ridge 85 and spaced apart from ridge 85 is stop 86. Stop 86 may extend laterally around lumen 72 as well, or it may comprise a protuberance of sufficient dimension to completely block plug body 77 from further movement into the housing 71, even if plug body 77 is composed of a deformable material.

To insert the valving member into housing 71, wearer grasps applicator 80 and inserts first end 82 supporting plug body 77 into the housing 71 until plug body 77 reaches the stop 86. This may be accomplished by configuring the plug body 77 from elastomer or foam as described above to be readily compressible upon application of pressure thereto (as from the ridge 85) and to be expandable upon release of pressure or release from a confined space (as in lumen 72 in all areas except region of ridge 85), as shown in FIG. 7.

Additionally, plug body 77 may be provided with an enlarged base portion 89 as is shown in FIG. 8. When plug body 77 is pushed beyond ridge 85, base portion 89 expands to serve as an anchor on ridge 85.

Applicator 80 is configured so that plug body 77 will not release from first end 82 of applicator 80 unless plug body 77

rests in the desired position as described above. The wearer then removes the applicator 80 and the urinary continence device 70 is in place to maintain continence. The string 78 extends from the end of the plug body 77 of the plug 76 through the housing 71 and extends from the human body for removal of the plug 76.

The plug body 77 provides occlusion within the housing 71 by virtue of its size and configuration, but also can be achieved by choice of materials for the plug body 77 and the housing 71. In some embodiments, the housing 71 may be made relatively stiff and the plug body 77 relatively flexible so that sealing against urine flow is accomplished when the plug body 77 conforms to the relatively stiff housing 71.

Alternatively, the housing 71 can be made relatively flexible and the plug body 77 relatively stiff so that occlusion occurs when the housing 71 conforms to the relatively stiff plug body 77. In yet another embodiment, both the plug body 77 and housing 71 will be flexible so that they conform to each other to provide sealing. It is within the skill of those knowledgeable in the art to select the materials for these members to provide an effective occluding device according to this embodiment of the invention.

When voiding is desired, a simple, continuous tug on the string 78 serves to unseat the plug body 77 from the housing 71. Preferably, the material of plug body 77 will resist pressure spikes which occur during physical activity to prevent urine leakage but when the wearer pulls on appendage 78, the plug body 77 material will elongate. The plug 77 slips past ridge 85 and is then easily removed from housing 71 within the urethra. Following bladder evacuation, a fresh plug 77 is inserted by means of an applicator into the housing 71 within the urethra.

FIGS. 9 though 11 illustrate a second type of urinary continence device 90 comprising housing 91 defining a lumen 92 and having a body 93, plate 94 and adhesive 95 on the plate 94 and a valving member 100 that functions for a limited number of uses and is comprised essentially of multiple occluding

members. In the embodiment shown in these figures, the multiple occluding members are a series of occluding bodies 102 joined together by a member or members that have a smaller diameter than the diameter of the occluding body 102 (for example by a string 104 or other appendage) and placed in the housing 91. The occluding body 102 may be comprised of a biocompatible material, such as polyurethane, polyethylene, polypropylene, nylon, latex, silicone, DYNAFLEX, KRATON, cellulose, foamed urethane, C-FLEX, polyvinylchloride and the like. For most uses, four to twelve occluding bodies 102 should be sufficient. It is preferable that the valving member 100 is pre-packed into the housing 91 for the ease of the wearer, as shown in FIG. 9, and inserted into the urethra by the wearer while positioned in the housing 91. String 104 extends from the occluding body 102 proximal to plate 94 through the housing 91 and extends from the human body for manipulation of the valving member 100.

Each occluding body 102 is sized so as not to occlude lumen 92 unless engaged by opening 96, as described below. It may be preferable to have means within housing 91 to prevent the occluding bodies 102 from bunching up within the lumen 92 above the opening 96 to block urine flow and/or to assist in the travel of each successive occluding body 102 towards the opening 96. Fingers 97 extend inwardly from the inside diameter of lumen 92 in the region above the opening 96 to lead each occluding body 102 in its path of travel and provide a urine path around the occluding body 102 when occluding body 102 is not in the opening 96.

In this embodiment, lumen 92 of housing 91 includes an opening 96 in the region above the plate 94 so as to provide an interference fit with an occluding body 102 to maintain continence. The opening 96 may be an area of reduced diameter in the lumen 92 of the housing 91, sized in relation to the size of the occluding bodies 102 to provide an interference fit. As shown in FIGS. 9-11, opening 96 alternatively comprises a ridge radially extending from the inside diameter of the lumen 92 of sufficient length and width to engage an

occluding body 102 so as to prevent urine flow. Additionally, each occluding body 102 is sized in relation to the diameter of the opening 96 of the lumen 92 of the housing 91 so as to form an interference fit with the opening so as to block the lumen 92 of the housing 91. The opening 96 may be deformable and the occluding bodies 102 relatively stiff so as to form the interference fit. Alternatively, the opening 96 may be relatively stiff and the occluding bodies 102 flexible to accomplish that engagement.

As the wearer needs to void, a simple continuous tug on the string 104 pulls one occluding body 102 through the opening 96, out of the housing 91, as shown in FIG. 10. The string 104 is now located in the area of the opening 96, and will not prevent urine flow so that voiding can be accomplished, with the arrows in FIG. 10 indicating an exemplary path of urine flow. As evacuation is complete, another tug pulls a second occluding body 102 into engagement with the opening 96 to cause occlusion, as shown in FIG. 11. An occluding body 102 removed from the housing 91 can be disposed of, if desired. An indicator, such as a color coded second-to-last occluding body 102 may be used to communicate to the wearer that there is only one more occluding body 102 remaining in the housing 91. After all occluding bodies 102 are used, the housing 91 must be removed and a new urinary continence device 90 inserted to continue with continence maintenance.

An alternative embodiment of the urinary continence device of the present invention is shown in FIG. 12 having valving member comprising an elastomeric type valve such as a duck bill type valve or a slit in an elastic member, shown in an open position in the figure. Urinary continence device 120 comprises housing 121 defining a lumen 122 and having a body 123, a plate 124 and adhesive 125 on the plate 124 and elastomeric type valve 126 positioned within said housing proximal to the plate 124. The elastomeric type valve 126 has converging members 127, 128 that are separable by a straw 129 that is inserted to separate the converging members 127, 128

to open the valve 126 to evacuate the bladder. Straw 129 may be configured so that urine flows through straw 129 for voiding, or straw 129 may merely separate the converging members 127, 128 to allow for urine flow from the device 120 in the region of the plate 124. Upon removal of the straw 129, the converging members 127, 128 automatically converge and close the valve 126 to maintain continence. A fresh straw 129 is used for each voiding.

Similarly, FIG. 13 illustrates another embodiment of the device of the present invention with a patch type valving member to regulate the device. Urinary continence device 130 includes housing 131 defining a lumen 132 and having a body 133, a plate 134 and adhesive 135 on the plate 134 and valving member 140 comprising a patch.

The patch 140 is shown more closely shown in FIG. 14. The patch 140 is preferably thin, about 0.005 to about 0.1 inch thick, and of flexible material such as KRATON, polyvinylchloride, or even a metalized or metal filled plastic such as MYLAR, a trademark of E.I. DuPont de Nemours of Wilmington, Delaware. The patch 140 will be secured to the exposed surface of the plate 134 by a bonding agent 145, which may be located on the patch 140 or alternatively on the exposed side of the plate 134. The bonding agent may be any bonding agent known in the art, such as adhesives, magnets or even a configuration of the interlocking surfaces of the plate 134 and patch 140 to promote adhesion. For example, the plate 134 and patch 140 may be provided with a VELCRO-type system for securing to each other. Alternatively, one of the plate 134 and patch 140 may be configured with a discontinuous surface and the other is provided with a surface that will mold into the discontinuous surface, effectively engaging the patch 140 mechanically to the housing 131 until removed.

When the wearer inserts the housing 131 into place using the method explained above, the patch 140 is placed over the opening of the housing 131 at the meatal region. As the patch is oversized, it will easily occlude the lumen 132 without precise alignment of the patch 140 on the lumen 132 to

5 maintain continence. Patch material overlapping the housing opening is floppy and will not restrict the comfort of the wearer. To void, the wearer peels the patch 140 off the housing 131. After voiding, a fresh patch 140 is put in place.

The preferred embodiment of the present invention is shown in FIGS. 15 and 16. The urinary continence device 150 includes housing 151 defining a lumen 152 and having a body 153, a plate 154 and adhesive positioned on the plate 155. In 10 use, the housing is inserted into the urethra and the plate 154 is adhered to the meatal region by means of the adhesive 155. Extending from housing 151 as a contiguous member or as a separate attachment secured by heat sealing, a layer of adhesive or the like, or provided as a separate piece is 15 valving member 160 comprising a cap. Those skilled in the art will recognize that a cap type valving member can take many forms, from simple to elaborate, so as to form a snap fit with the housing 151 to close the lumen 152 to maintain continence. The cap type valve is preferably configured so as to allow for 20 high internal pressures to maintain continence and low pull forces to open. One such embodiment is illustrated in the figures.

Valving member 160 comprises cap top 162 attached to housing 151 by a tab 164 extending from plate 154. Configured 25 as a part of housing 151 or secured to plate 154 by heat sealing, adhesive or the like is ridge 165, configured so as to define an aperture 166 of reduced diameter and a void 167 of generally larger diameter than aperture 166. Protruding 30 from cap top 162 is fitting 168 of approximately the same diameter and size as aperture 166 and conformable knob 169 of approximately the same diameter and size as void 167. The interaction of fitting 168 and conformable knob 169 with the aperture 166 and void 167 respectively forms a snap fit, thereby locking the cap top 162 and closing the valving member 35 160 to maintain continence.

Preferably the tab 164 is a flexible hinge, a material such as those described above for the housing and should be

made having sufficient flexibility and rigidity so that when tab 164 is activated to open the device 150, the tab 164 goes to a preset position that will position the valving member 160 away from the stream of urine during voiding. Extending from the cap top 162 is a second tab 163 which the wearer can pull to open the cap. Once evacuation is completed, the wearer will push to close the cap top 162 shut and maintain continence.

A device 150 according to this embodiment of the present invention is shown ready for insertion on an applicator 30 in FIG. 17. Reference to FIG. 5 and the accompanying description should be made for the applicator 30.

FIGS. 18 - 20 shows an alternative embodiment 180 of the present invention including housing 181 defining a lumen 182 and having a body 183, a plate 184 and adhesive 185 on the plate 184. In use, housing 181 is inserted into the urethra and plate 184 is adhered to the meatal region by means of adhesive 185. Valving member 190 is positioned within the housing 181.

A lever 191 is provided to swingably mount a cylindrical valve 193 for swinging the valve 193 between closed and open positions, shown in FIG. 19 and FIG. 20, respectively, with respect to the lumen 182. The lever 191 has lever end 192 on which the valve 193 is rotatably mounted. Resilient means provide a sealing engagement between valve 193 and lumen 182. This means resides in the outwardly curved, resilient side portions 187 extending from housing 181.

The figures illustrate one mechanism to accomplish a sealing engagement for this embodiment of the present invention. Resilient means are provided to urge the valve 193 against the lumen 182 below the plate 184. The inherent resiliency of the side portions 187 causes the valve 193 to bias against the side portions 187 to create a good seal in the device 180.

Valve 193 is provided with a bore 194 therethrough, for urine flow. As illustrated in FIGS. 19 and 20, the lever 191 may be swung to either of two positions to control continence.

When lever 191 is in the position shown in FIG. 19, the bore 194 is engaged with side portions 187, and occlusion will occur in the housing 181 above the valving member 190. When swung to its open position, shown in FIG. 20, urine will readily flow out of the lumen 182 through bore 194 for evacuation of the bladder.

In a preferred embodiment of the device shown in FIGS. 18 - 20, valving member 190 will be configured so as to require that lever 191 be swung a sufficient distance so that it is away from the urine stream when voiding is accomplished. As shown in these figures, lever 191 must be swung more than 90 degrees, and optimally, the lever 191 will be swung a full 180 degrees so that the lever 191 is not wet during voiding. In another variation of this embodiment, valving member 190 may be provided with a catch 195 to prevent activation until lever 191 has been swung a sufficient distance for those purposes.

In a female wearer, lever 191 will preferably be configured so as to rest over the vaginal opening when closed for maximal comfort and ease, i.e., in a longitudinal position on the wearer, not laterally. Upon opening, lever 191 will rest proximal to the clitoris. Placing the device so that the lever 191 rests and swings longitudinally, rather than laterally, will reduce the risk of accidental opening of the device 180, and therefore accidental voidings due to movement and activity of the wearer.

FIG. 21 illustrates an alternative configuration of the housing, particularly useful for female wearers, for use with a urinary continence device 210 according to the present invention. Device 210 includes housing 211 defining a lumen 212 and having body 213 and plate 214. As shown, plate 214 is a member having thickness and provided with sloping sides to enlarge the top surface of the plate 214 that, in use, adheres to the wearer. Adhesive 215 is positioned on the enlarged surface of the plate 214. In use, housing 211 will rest within the folds of the labia minora. The enlarged surface and the enlarged thickness of the plate 214 on which the adhesive 215 is placed provides enhanced anchoring and

preferably enhanced sealing of the device to the wearer. FIG. 21 also provides an example of an alternative configuration for body 213, shaped so that lumen 212 is oval.

FIGS. 22 and 23 illustrate the urinary continence device of the present invention, including one valving member as described above with reference to FIGS. 7 and 8, but having adhesive 13 present on the body of the housing for anchoring the device in the human body. Reference should be made to the appropriate description above for the removable plug type valving member. A urinary continence device of the present invention having adhesive 13 on the body for anchoring is particularly useful for those devices in which a valving member is inserted each time voiding is accomplished. Adhesive 13 may be in a continuous layer on body, but preferably will be positioned in the region of the body where the valving member rests to maintain continence. With this preferred use, prior to insertion of the device in the human body, the body of the device can be collapsed in the region in which the adhesive is positioned, as shown in FIG. 22. After the device is slid into the urethra, the valving member is inserted, forcing the collapsed body open to press the adhesive against the walls of the urethra, as shown in FIG. 23. Of course, other types of valving members can be incorporated into the urinary continence device of the present invention having adhesive 13 present on the body of the housing for anchoring the device in the human body.

The above-described embodiments utilize valving members that are actuated by the wearer of the device. One skilled in the art will instantly realize that other valving members actuatable by the wearer of the device could be used in a urinary continence device according to the present invention. For example, any valving member that is manipulated by the wearer using his or her hands may be incorporated into the device of the present invention. Additionally, valving members that are actuated remotely by the wearer may be utilized with the device of the present invention. The wearer may manipulate a portable magnet to selectively move a steel

or magnetic valving member in the urinary continence device in the wearer to open and/or close the valving member.

Alternatively, a radio controlled valving member may be used, such as a radio controller that can actuate a solenoid valve.

5 Similarly, a check valve, actuatable by fluid of any type such as urine, can be used as the valving member of a urinary continence device according to the present invention.

It is also within the teachings of the present invention to incorporate a pressure relief valving member. Such a 10 device would be particularly useful for a spinal cord injury patient, for whom sustained bladder pressures above 45 cm of water can be dangerous, due to the risk of back flow of urine up the ureters and thus potential kidney damage. A pressure relief valving member is configured to intentionally leak at 15 45 cm of water, or greater, if the pressure is sustained for a period of time, optimally five minutes, but maintains continence with pressure peaks such as a high pressure cough (150 cm of water), laughter (90 cm of water) or picking up a heavy object (90 cm of water). Such a valving member may 20 function hydraulically by moving fluid from one chamber to another, which requires both pressure and time prior to opening the pressure relief valving member.

The urinary continence device of the present invention provides benefits over known devices. The housing is inserted 25 by the wearer and does not require the services of a health care professional or surgical implantation. The housing is inserted by the wearer once for an extended period of time; it will remain for the any number of voidings that occur during that period. The housing is configured so as to reduce the 30 risk of introduction of bacteria into the bladder and of trauma to the bladder and the urethra. Finally, the housing is a lumen of approximately the same diameter as a normal urethra during urination. It thus provides a sufficient opening for urine flow close to that of a normal urethra and therefore promotes normal duration for evacuation. In 35 addition, the invention can provide for protection to shield the device from urine which could damage the bond between the

adhesive and the tissue.

While the invention has been particularly shown and described with reference to the aforementioned embodiments, it will be understood by those skilled in the art that various changes in form, composition and detail may be made therein without departing from the spirit and scope of the invention. It is envisioned that the device of the present invention and/or any or all of its components can be coated with or have integral to its components, therapeutic agents of a wide variety for release into the urinary tract. The purpose of these therapeutic agents, for example, could be to reduce pain or the risk of infection from the device to the wearer, or the agents could be designed to treat the wearer for conditions unrelated to the device itself. The agents could be made to release immediately or release at a predetermined rate over time. Any modification to the shape, configuration and/or composition of the elements comprising the invention is within the scope of the present invention.

CLAIMS

## WHAT IS CLAIMED IS:

1. A urinary continence device comprising:

a housing defining a lumen and having

5 a body insertable in a urethra of a human body,  
a plate extending from said body and adapted to be  
retained on the human body for multiple  
voidings by adhesive positioned on the surface  
of the plate proximal to the body; and

10 a valving member.

2. The device of claim 1 wherein the housing comprises a  
biocompatible material selected from the group consisting of  
polyurethane, polyethylene, polypropylene, nylon, latex,  
15 silicone, biocompatible thermoplastic elastomer, foamed  
biocompatible thermoplastic elastomer, foamed urethane,  
cellulose, and polyvinylchloride.

3. The device of claim 1 wherein the body is tubular.

20 4. The device of claim 3 wherein the end of the body distal  
to the plate is blunt.

5. The device of claim 3 wherein the end of the body distal  
25 to the plate is tapered.

6. The device of claim 3 wherein the end of the body distal  
to the plate is rounded.

30 7. The device of claim 1 wherein the adhesive is positioned  
on the plate in a continuous layer.

8. The device of claim 1 wherein the adhesive is positioned  
on the plate in a discontinuous layer.

35 9. The device of claim 1 wherein the adhesive is selected  
from the group consisting of hydrogel adhesives,

polyvinylether-based adhesives, hydrocolloid, acrylic-based adhesives, synthetic gum rubber adhesives and natural gum rubber adhesives.

- 5        10. The device of claim 1 wherein the body is sized in length so that when the plate is retained on the human body, the body extends into the urethra proximal to the *meatus urinarius*.
- 10        11. The device of claim 1 wherein the body is sized in length so that when the plate is retained on the human body, the body extends beyond the sphincter muscle.
- 15        12. The device of claim 1 further comprising one or more sealing rings extending from the outside diameter of the body of the housing.
- 20        13. The device of claim 1 further comprising a guiding member secured to the exposed surface of the plate and extending from said plate.
- 25        14. The device of claim 1 wherein said valving member comprises a removable plug.
- 30        15. The device of claim 14 wherein the housing further comprises a stop member positioned within the lumen so as to prevent the removable plug from migrating out of the body of the housing.
- 35        16. The device of claim 14 wherein the removable plug comprises a plug body and an appendage adapted to be grasped by a user for removal of the removable plug.
17. The device of claim 16 wherein the plug body comprises a biocompatible material selected from the group consisting of polyurethane, polyethylene, polypropylene, nylon, latex, silicone, thermoplastic elastomer, foamed thermoplastic elastomer, foamed urethane and polyvinylchloride.

18. The device of claim 16 wherein the plug body is substantially spherical.

5 19. The device of claim 16 wherein the plug body is substantially cylindrical.

20. The device of claim 19 wherein the plug body has an expanded base portion.

10 21. The device of claim 14 wherein the housing is formed so as to be relatively stiff and the removable plug is formed so as to be relatively flexible.

15 22. The device of claim 14 wherein the housing is formed so as to be relatively flexible and the removable plug is formed so as to be relatively stiff.

20 23. The device of claim 14 wherein the housing and the removable plug are formed so as to be relatively flexible.

24. The device of claim 14 wherein the valving member further comprises an applicator for inserting the removable plug into the housing.

25 25. The device of claim 14 wherein the end of the body distal to the plate is tapered.

30 26. The device of claim 1 wherein the valving member comprises multiple occluding members positioned within the body of the housing and wherein the housing further comprises an opening for engaging said multiple occluding members so as to occlude the lumen of the housing.

35 27. The device of claim 26 wherein the housing further comprises positioning members extending laterally and downwardly from the inside diameter of the body proximal to the opening for positioning of the multiple occluding members.

28. The device of claim 26 wherein the multiple occluding members comprises multiple occluding bodies secured together by a joining member that extends from the housing out of the human body.

5

29. The device of claim 26 wherein the opening is deformable and the multiple occluding members are relatively stiff.

10 30. The device of claim 26 wherein the opening is relatively stiff and the multiple occluding members are deformable.

15 31. The device of claim 26 wherein the multiple occluding members are formed of a material selected from the group consisting of polyurethane, polyethylene, polypropylene, nylon, latex, silicone, thermoplastic elastomer, foamed thermoplastic elastomer, foamed urethane and polyvinylchloride.

20 32. The device of claim 26 wherein the end of the body distal to the plate is tapered.

33. The device of claim 1 wherein the valving member comprises:

25 an elastomeric body positioned within said housing having converging elements configured so as to sealingly engage each other for restricting flow through said housing and to conform upon application of pressure thereto for allowing flow through said housing; and

30 a member configured to apply pressure to the converging elements and to allow flow from the device.

34. The device of claim 33 wherein the end of the body of the housing distal to the plate is tapered.

35 35. The device of claim 1 wherein the valving member comprises a cap, the cap configured to interlock with the housing to provide a snap fit to occlude the lumen of the

housing.

36. The device of claim 35 wherein the cap interlocks with a ridge protruding from the exposed surface of the plate.

5

37. The device of claim 36 wherein the ridge defines an aperture and a void having a larger diameter than the diameter of the aperture and wherein the cap further comprises a fitting and a conformable knob extending from one surface thereof;

10

wherein the fitting and the knob are positioned and sized so as to form a snap fit with the aperture and the void.

15

38. The device of claim 35 wherein the cap is secured to the housing by a flexible member.

20

39. The device of claim 1 wherein the valving member comprises a patch secured to the surface of the plate other than the surface of the plate on which the adhesive is positioned.

40. The device of claim 39 wherein the patch is secured to the surface of the plate by an adhesive.

25

41. The device of claim 39 wherein the patch is secured to the surface of the plate by a magnetic force.

30

42. The device of claim 39 wherein the surface of the plate to which the patch will be secured is configured with a discontinuous surface to which the patch will secure.

43. The device of claim 39 wherein the end of the body distal to the plate is tapered.

35

44. The device of claim 1 wherein the valving member comprises a valve having a bore therethrough positioned within the housing and rotatable to an open and closed

position to control fluid flow.

45. The device of claim 44 wherein the valve is rotatably mounted on a lever, and the valve is positioned within outwardly curved, resilient side portions of the lumen in the region of the lumen proximal to the plate.

5  
10 46. The device of claim 44 wherein the valving member further comprises a catch to prevent activation of the valving member prior to sufficient rotation of the lever.

47. A urinary continence system comprising:  
15 a housing defining a lumen and having  
a body insertable in a urethra of a human body,  
a plate extending from said body and adapted to be  
retained on the human body for multiple  
voidings by adhesive positioned on the surface  
of the plate proximal to the body;  
20 a valving member; and  
an applicator.

25 48. The system of claim 47 wherein the applicator comprises a tubular member sized so as to exert pressure on the plate on the surface of the plate opposite to that surface of the plate on which the adhesive is positioned.

49. The system of claim 48 wherein the valving member comprises a removable plug.

30 50. The system of claim 49 wherein the housing further comprises a stop member positioned within the lumen so as to prevent the removable plug from migrating out of the body of the housing.

35 51. The system of claim 48 wherein the valving member comprises multiple occluding members positioned within the body of the housing and wherein the housing further comprises

an opening for engaging said multiple occluding members so as to occlude the lumen of the housing.

52. The system of claim 48 wherein the valving member comprises an elastomeric body positioned within said housing having converging elements configured so as to sealingly engage each other for restricting flow through said housing and to conform upon application of pressure thereto for allowing flow through said housing; and

10 a member configured to apply pressure to the converging elements and to allow flow through the device.

53. The system of claim 48 wherein the valving member comprises a patch secured to the surface of the plate other than the surface of the plate on which the adhesive is positioned.

54. The system of claim 48 wherein the valving member comprises a cap, the cap configured to interlock with the housing to provide a snap fit to occlude the lumen of the housing.

55. The system of claim 48 wherein the valving member comprises a valve having a bore therethrough positioned within the housing and rotatable to an open and closed position to control fluid flow.

56. The system of claim 47 wherein the applicator comprises:  
an applicator body;  
30 a support member extending from the applicator body for resting the urinary continence device during insertion into the human body; and  
an applicator head extending from the applicator body for supporting the urinary continence device during insertion into the human body.

57. The system of claim 56 wherein the applicator head has a rounded edge and is configured so as to extend through the lumen of the housing of the urinary continence device to facilitate insertion into the human body.

5

58. The system of claim 56 wherein the valving member comprises a removable plug.

10 59. The system of claim 58 wherein the housing further comprises a stop member positioned within the lumen so as to prevent the removable plug from migrating out of the body of the housing.

15 60. The system of claim 56 wherein the valving member comprises an elastomeric body positioned within said housing having converging elements configured so as to sealingly engage each other for restricting flow through said housing and to conform upon application of pressure thereto for allowing flow through said housing; and  
20 a member configured to apply pressure to the converging elements and to allow flow from the device.

25 61. The system of claim 57 wherein the valving member comprises a patch secured to the surface of the plate other than the surface of the plate on which the adhesive is positioned.

30 62. The system of claim 57 wherein the valving member comprises a cap, the cap configured to interlock with the housing to provide a snap fit to occlude the lumen of the housing.

35 63. The system of claim 56 wherein the valving member comprises a valve having a bore therethrough positioned within the housing and rotatable to an open and closed position to control fluid flow.

64. A method of controlling urinary incontinence comprising:  
providing a urinary continence device comprising a  
housing defining a lumen and having a body to be inserted in  
the urethra of a human body, a plate extending from said body  
5 and adapted to be retained on the human body through multiple  
voidings by adhesive positioned on the surface of the plate  
proximal to the body, and a valving member;

inserting the urinary continence device in the urethra  
until the plate abuts the *meatus urinarius*;

10 securing the plate of the urinary continence device to  
the human body;

manipulating the valving member to occlude the flow of  
urine from the human body and to allow the flow of urine from  
the human body.

15

65. The method of claim 64 wherein the step of securing the  
plate to the human body comprises adhering the plate thereto  
by activating the adhesive.

20

66. The method of claim 64 wherein the valving member  
comprises a removable plug, and wherein the step of  
manipulating the valving member comprises inserting the  
removable plug into the housing to occlude urine flow and  
removing the removable plug from the housing to allow urine  
25 flow.

67. The method of claim 64 wherein the valving member  
comprises multiple occluding bodies joined together by a  
joining member, and the step of manipulating the valving  
30 member comprises pulling on the joining member so as to  
position one of said multiple occluding bodies so as to  
occlude or not occlude the lumen of the housing.

68. The method of claim 64 wherein the valving member  
35 comprises an elastomeric body positioned within said housing  
having converging elements configured so as to sealingly  
engage each other for restricting flow through said housing

and to conform upon application of pressure thereto for allowing flow through said housing;  
and wherein the step of manipulating the valving member comprises applying pressure to the converging elements with a member configured to apply pressure to the converging elements to open the converging elements to allow flow through the device and releasing the pressure on the converging elements by removing the member so as to allow the converging elements to sealingly engage each other to restrict flow through the device.

69. The method of claim 64 wherein the valving member comprises a patch and the step of manipulating the valving member comprises securing the patch to the surface of the plate other than the surface of the plate on which the adhesive is positioned to occlude urine flow and removing the patch from the surface of the plate to allow urine flow.

70. The method of claim 64 wherein the valving member comprises a cap, the cap configured to interlock with the housing to provide a snap fit to occlude the lumen of the housing, and the step of manipulating the valving member comprises removing the cap from the housing to allow urine flow and securing the cap to the housing to occlude the lumen.

71. The method of claim 64 wherein the valving member comprises a rotatable valve having a bore therethrough positioned within the housing and wherein the step of manipulating the valving member comprises rotating the rotatable valve to a position in which the bore extends the lumen of the housing so that the urinary continence device is open to allow urine flow and rotating the rotatable valve to a position in which the bore blocks the lumen of the housing so that the urinary continence device is closed to occlude fluid flow.

72. The method of claim 64 further comprising the step of: removing the urinary continence device.

5 73. The method of claim 72 wherein the step of removing the urinary continence device is accomplished by use of mechanical force.

10 74. The method of claim 72 wherein the step of removing the urinary continence device is accomplished by use of a releasing agent.

15 75. A urinary continence device comprising:  
a housing defining a lumen and having  
a body insertable in a urethra of a human body and  
adhesive positioned on the external surface of the  
body, and  
a plate extending from said body and adapted to rest  
proximal to the human body; and  
a valving member;  
20 said device adapted to be retained in the human body for  
multiple voidings.

25 76. The device of claim 75 wherein the adhesive is selected  
from the group consisting of hydrogel adhesives,  
polyvinylether-based adhesives, hydrocolloid, acrylic-based  
adhesives, synthetic gum rubber adhesives and natural gum  
rubber adhesives.

30 77. The device of claim 75 wherein the valving member  
comprises a removable plug.

35 78. The device of claim 75 wherein the valving member  
comprises multiple occluding members positioned within the  
body of the housing and wherein the housing further comprises  
an opening for engaging said multiple occluding members so as  
to occlude the lumen of the housing.

79. The device of claim 75 wherein the valving member comprises:

an elastomeric body positioned within said housing having converging elements configured so as to sealingly engage each other for restricting flow through said housing and to conform upon application of pressure thereto for allowing flow through said housing; and

a member configured to apply pressure to the converging elements and to allow flow from the device.

10

80. The device of claim 75 wherein the valving member comprises a cap, the cap configured to interlock with the housing to provide a snap fit to occlude the lumen of the housing.

15

81. The device of claim 75 wherein the valving member comprises a patch secured to the surface of the plate other than the surface of the plate on which the adhesive is positioned.

20

82. The device of claim 75 wherein the valving member comprises a valve having a bore therethrough positioned within the housing and rotatable to an open and closed position to control fluid flow.

1 / 8

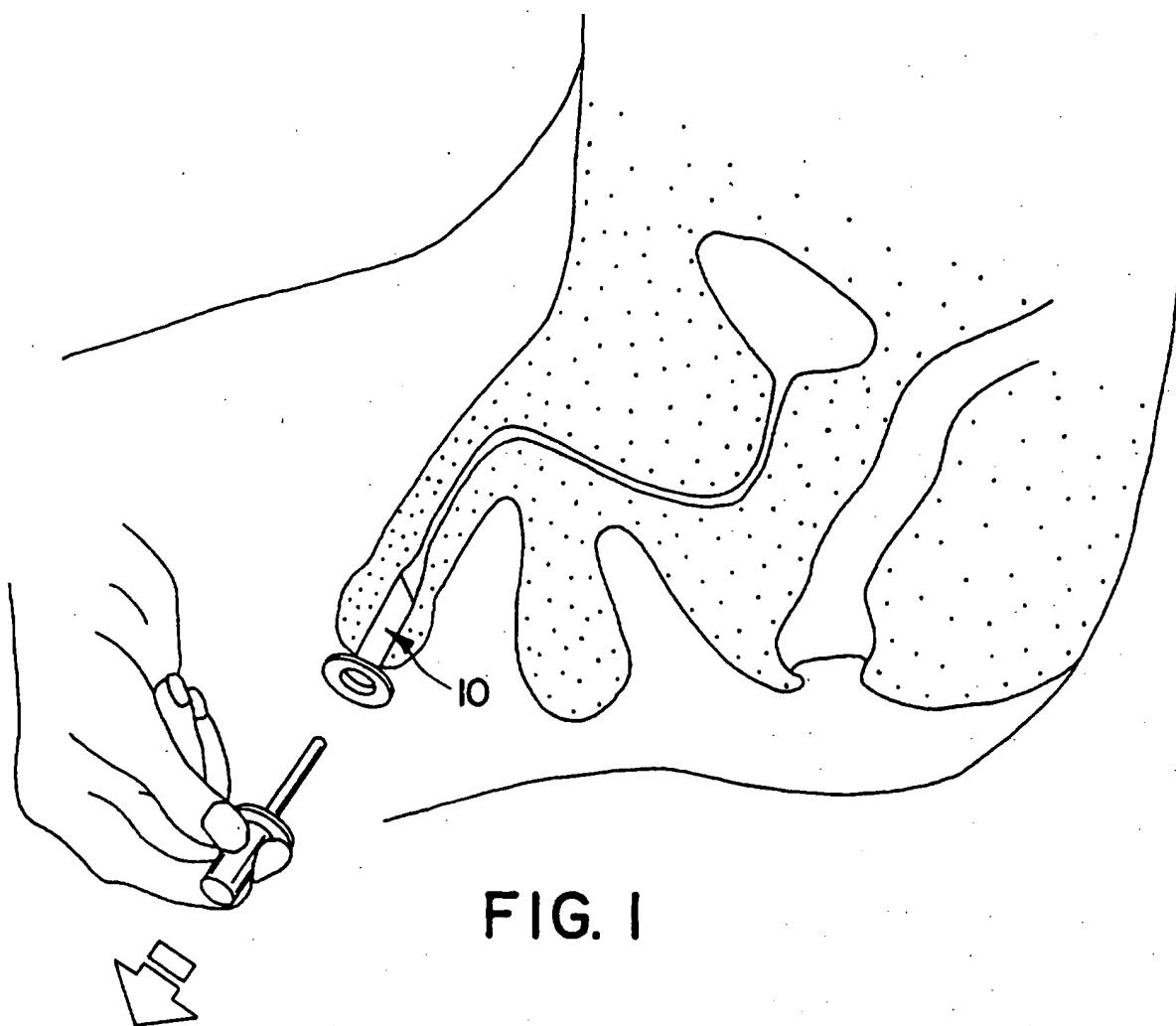


FIG. 1

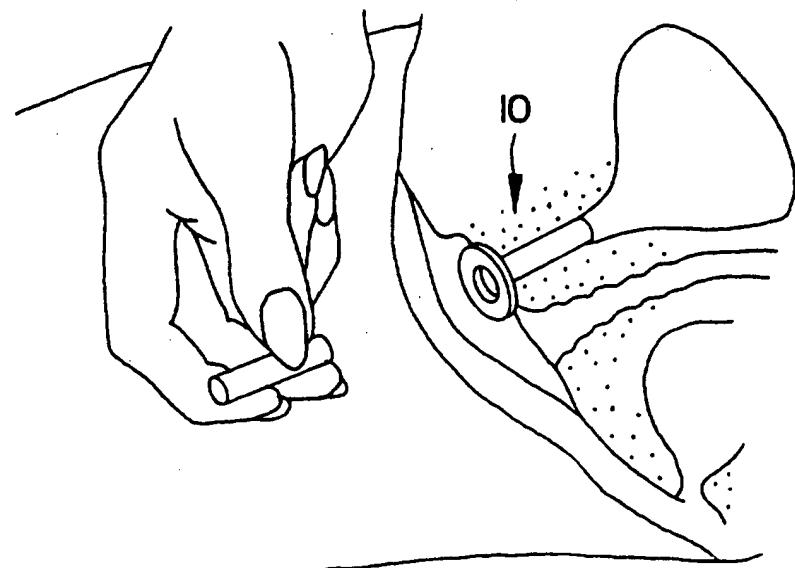


FIG. 2

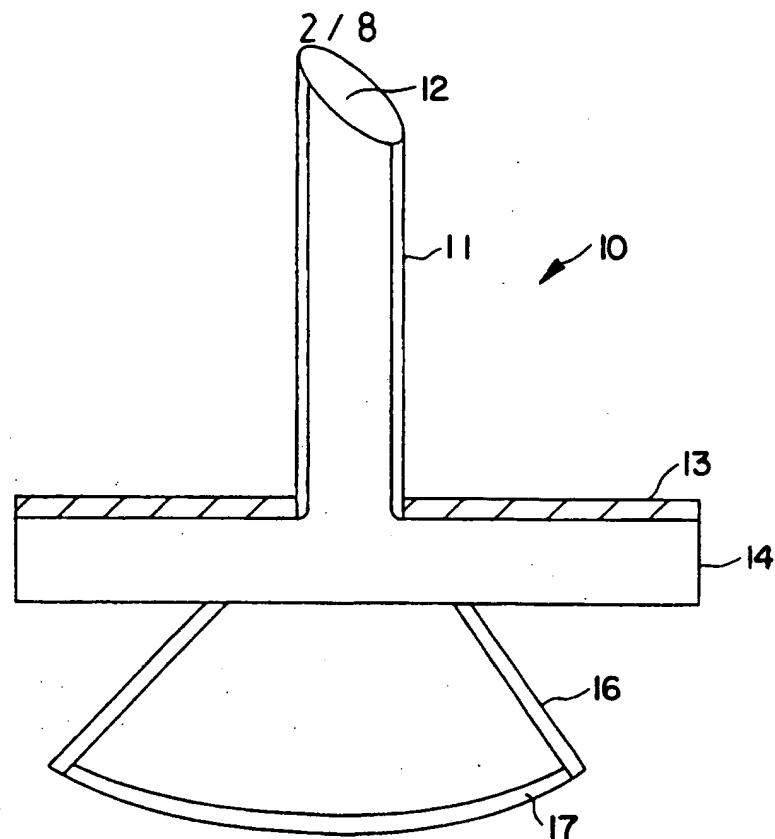


FIG. 3

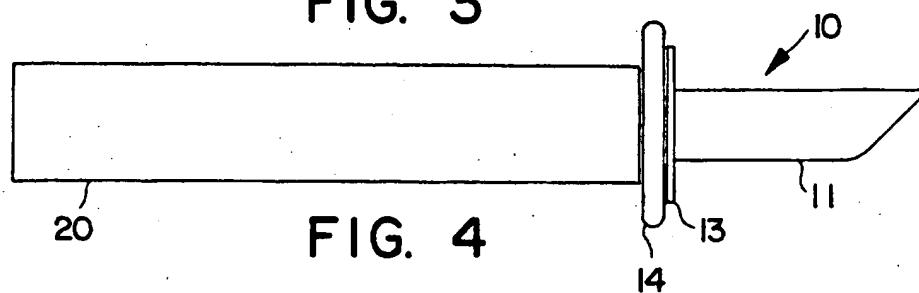


FIG. 4

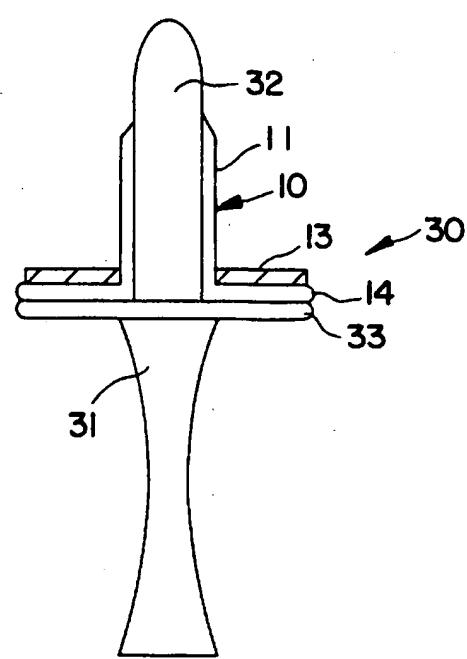


FIG. 5

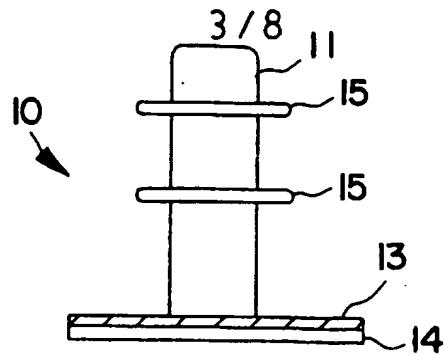


FIG. 6

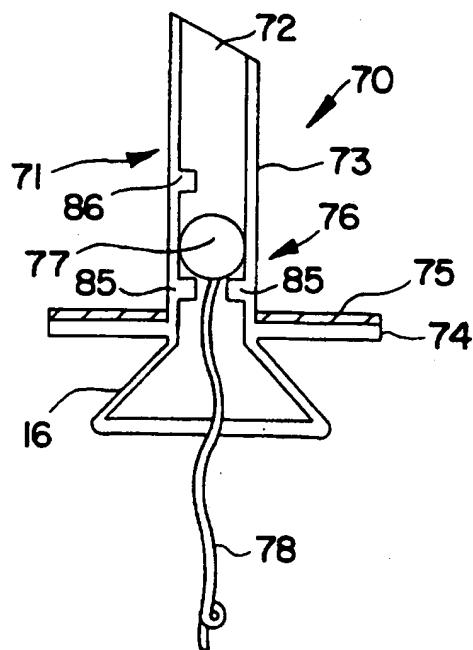


FIG. 7

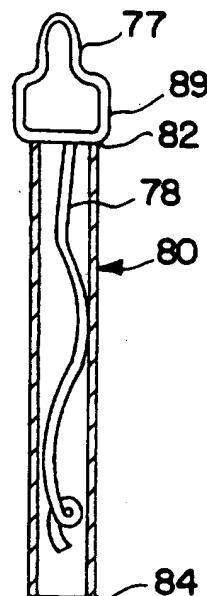
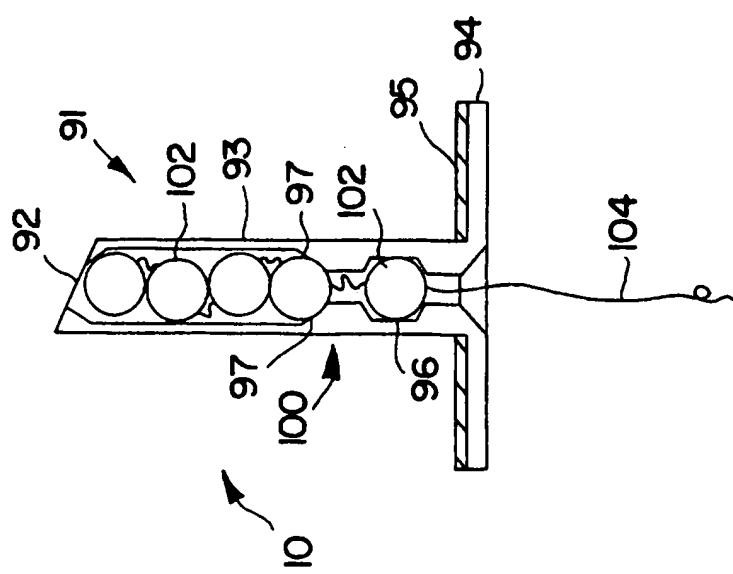
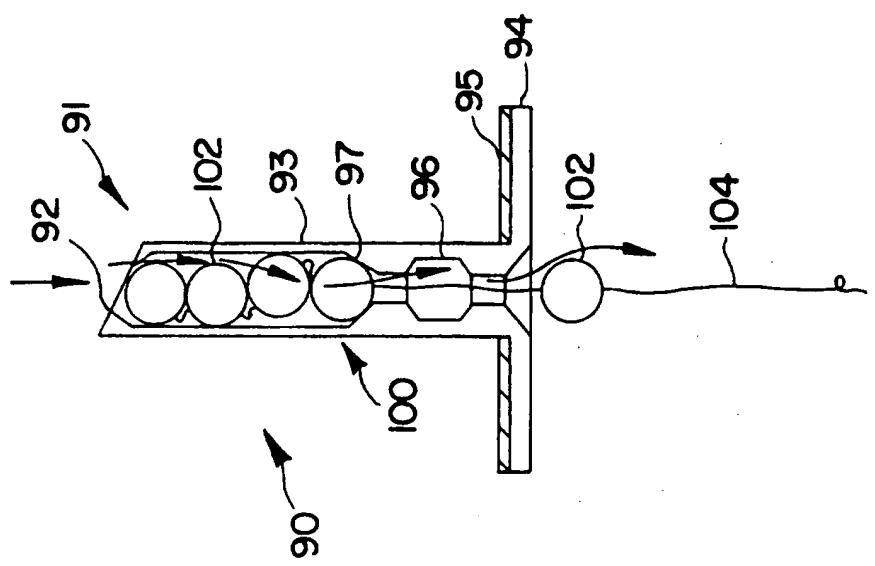
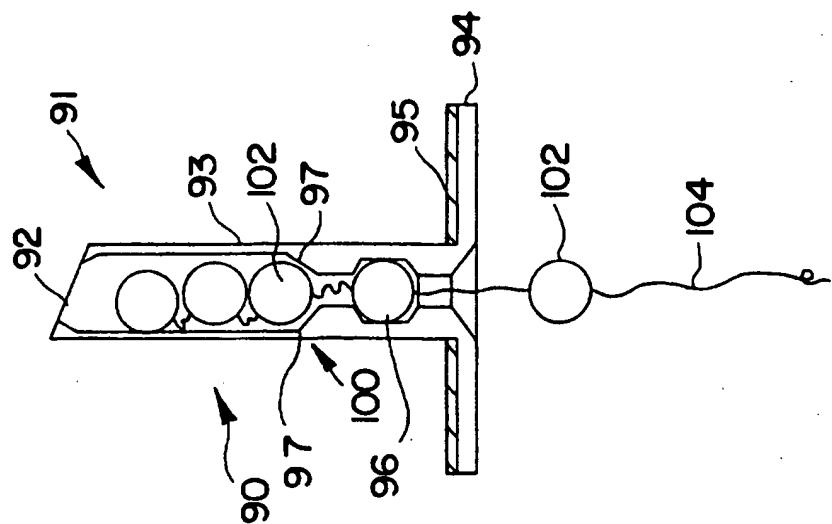


FIG. 8

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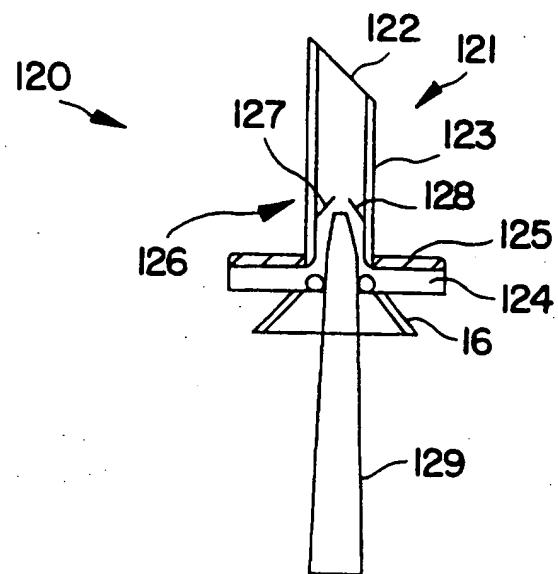


FIG. 12

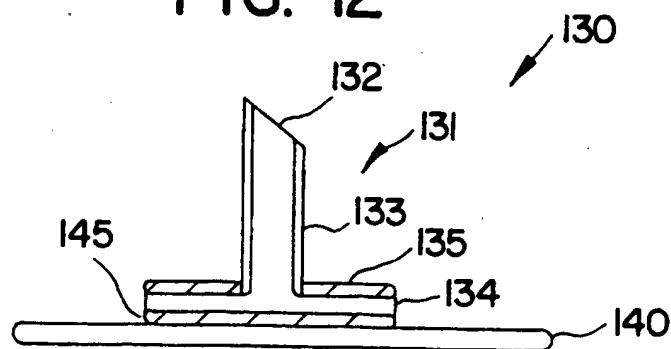


FIG. 13

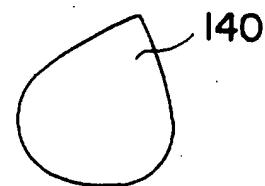
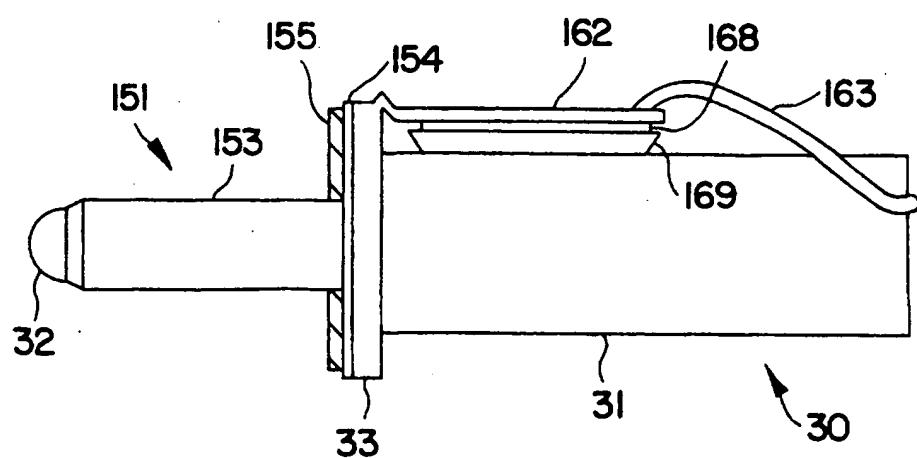
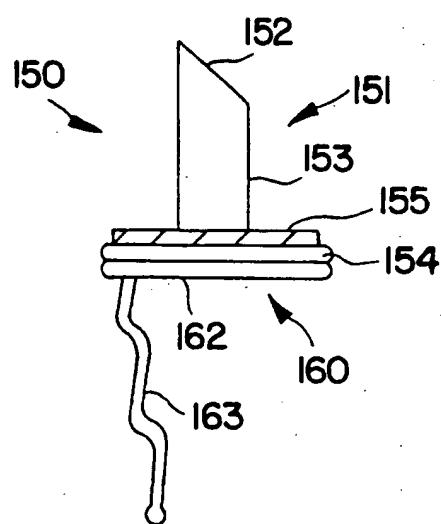
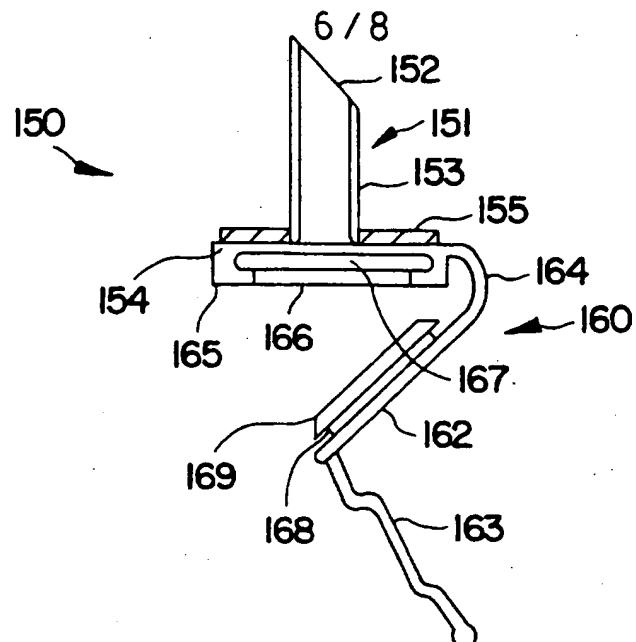
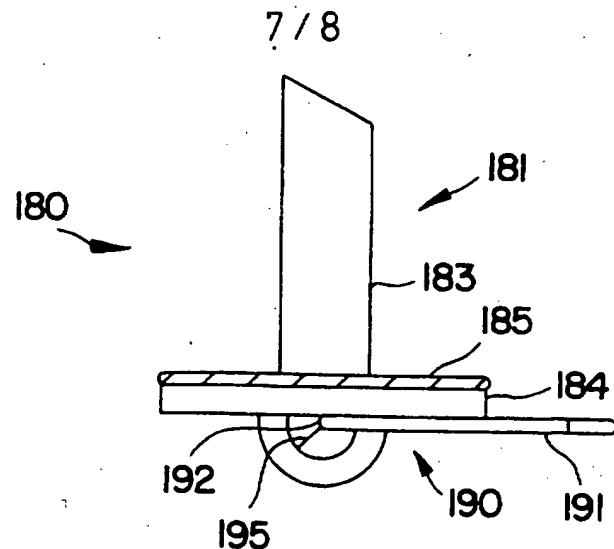
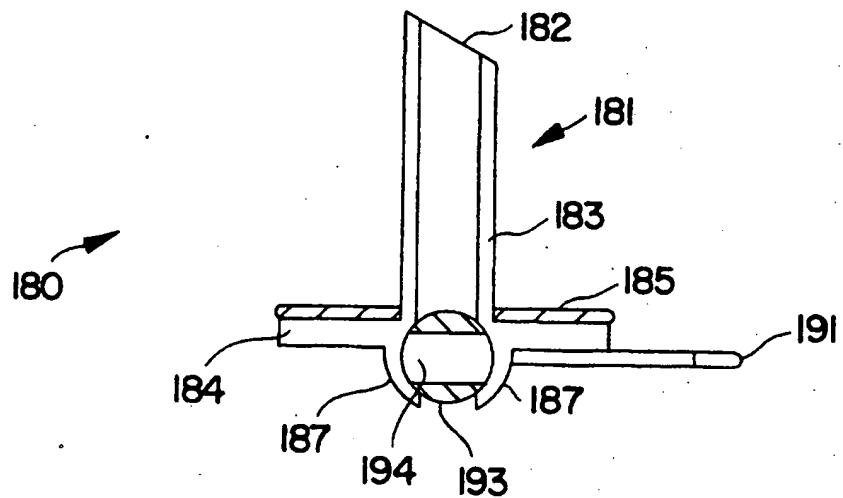
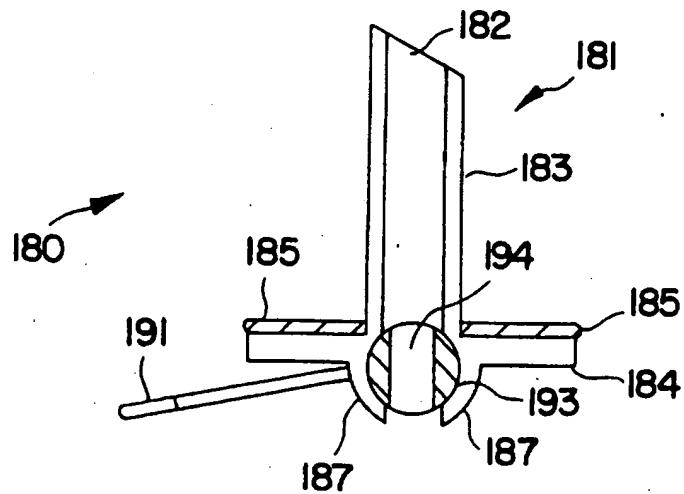


FIG. 14



**FIG. 18****FIG. 19****FIG. 20**

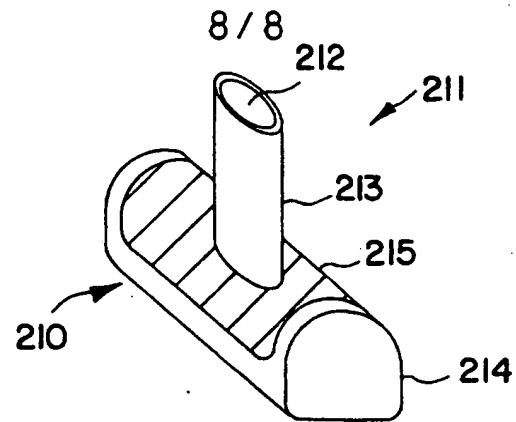


FIG. 21

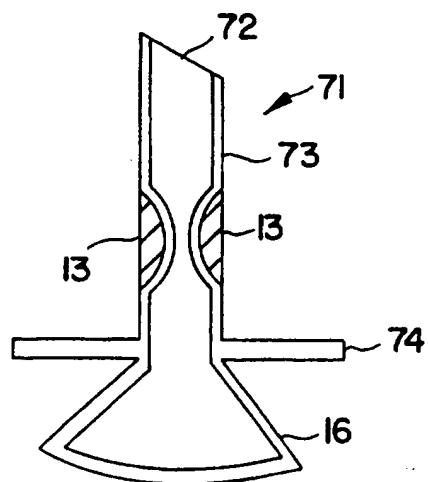


FIG. 22

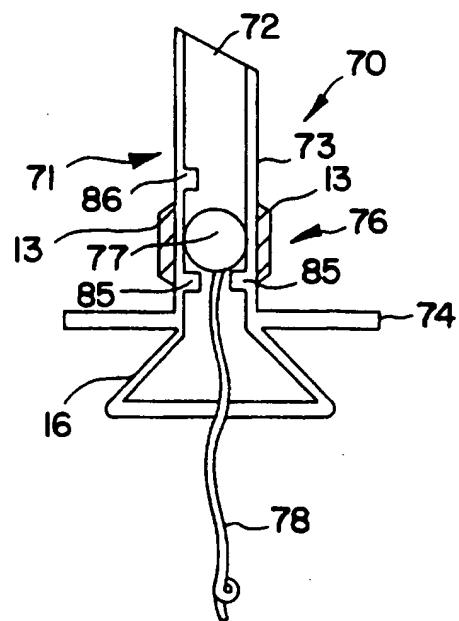


FIG. 23

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/18333

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61F 2/00

US CL : 600/029

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/DIG. 24; 600/029-032

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 93/24075 A (RAM et al) 09 December 1993, entire document.	1-11, 13-25, 35, 38, 47-50, 52, 54, 56-60, 62, 64-66, 68, 70, 72-66, 79, 80
Y	US 4,261,340 A (BAUMEL et al) 14 April 1981, entire document.	1-11, 13-25, 35, 38, 47-50, 52, 54, 56-60, 62, 64-66, 68-70, 72-77, 79, 80

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Date of mailing of the international search report

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(71) Applicant: UROMED CORPORATION [US/US]; 64A Street, Needham, MA 02194 (US). (72) Inventors: MAXFIELD, Michelle, D.; 1006 Broadway, Somerville, MA 02144 (US). CERIER, Jeffrey, C.; 11 Orchard Street, Franklin, MA 02038 (US). (74) Agents: LORUSSO, Anthony, M. et al.; Lorusso & Loud, 440 Commercial Street, Boston, MA 02109 (US).			
<b>(54) Title:</b> METHOD AND DEVICE FOR CONTROLLING URINARY INCONTINENCE			
<b>(57) Abstract</b> <p>This invention is a novel urinary continence device and a method of controlling urinary incontinence utilizing that device; the device comprising a housing (10), defining a lumen (12), having a body (11) for insertion into the urethra, a plate (14), and a valving member; the plate (14) and/or the body (11) having an adhesive (13) or other sealing means thereon, wherein the adhesive (13) or other sealing means secures the device to the human body, generally to the tissues surrounding the meatus urinary and/or to the urethral walls. The housing (10) may remain in the body for an extended period of time. The valving member blocks the flow of urine in the urethra until voiding is desired. In a preferred embodiment, the valving member is a cap (160) configured so as to form a snap fit with an internal lumen of the housing.</p>			

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